



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

AUG - 4 2004

Mr. John Morley
President
Natural Factors Nutritional Products, Inc.
1111 80th Street S.W.
Suite 100
Everett, Washington 98203

Dear Mr. Morley:

This is in response to your letter to the Food and Drug Administration (FDA) dated June 23, 2004. Your letter was submitted pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Natural Factors Nutritional Products, Inc. is making the following claim, among others, for the product **SlimStyles™ Weight Loss Drink Mix with PGX™** which it intends to market as a dietary supplement:

“The revolutionary new SlimStyles Meal Replacement Program....”

21 U.S.C. 321(ff) defines the term “dietary supplement.” As defined by the Act, dietary supplements do not include products represented for use as conventional foods, 21 U.S.C. 321(ff)(2)(B). In your submission, you state that the intended use of this product is, in part, as a drink mix intended for use as a component of a meal replacement. Therefore, this product appears to be represented for use as a conventional food and is not a dietary supplement within the meaning of 21 U.S.C. 321(ff) and claims made for it are not subject to 21 U.S.C. 343(r)(6).

Instead, this product appears to be a conventional food that must meet the regulatory requirements that apply to conventional foods rather than those requirements that apply to dietary supplements. Briefly, it must bear nutrition labeling in accordance with 21 CFR 101.9 and claims may be made for the product in its labeling if they are claims defined by 21 U.S.C. 403(r)(1) or 21 U.S.C. 321(g)(1)(C) that may be made for conventional foods. Additionally, under the Act, any ingredient intentionally added to a conventional food must be used in accordance with a food additive regulation unless it is generally recognized as safe (GRAS) among qualified experts for its intended use in food. A food ingredient that is not GRAS or an approved food additive causes a food to be adulterated under 21 U.S.C. 342(a)(2)(C) and cannot be legally marketed in the U.S. If you intend to

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Page 2 - Mr. John Morley

market this product as a conventional and you have any questions about the status of its ingredients, you should direct them to FDA's Office of Food Additive Safety (HFS-200), 5100 Paint Branch Parkway, College Park, MD 20740.

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Walker", with a stylized flourish at the end.

Susan J. Walker, M.D.

Director

Division of Dietary Supplement Programs

Office of Nutritional Products, Labeling
and Dietary Supplements

Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

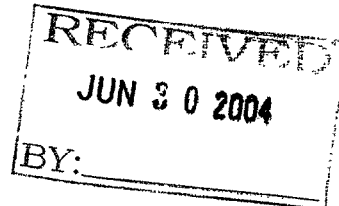
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Seattle District Office, Office of Compliance, HFR-PA340

Natural Factors Nutritional Products Inc.

June 23, 2004

Food and Drug Administration
Office of Special Nutritionals
Center for Food Safety and Applied Nutrition
200 C Street SW
Washington, DC 20204



Dear Sir or Madam:

This is to provide the required information to comply with our obligation under DSHEA labeling regulations.

Supplement: SlimStyles™ Weight Loss Drink Mix with PGX™
6 Flavors: Natural Chocolate, Natural Vanilla, Natural
Strawberry, Natural Mango/Peach, Natural Piña Colada,
Natural Mocha

Manufacturer, packer: Natural Factors Nutritional Products, Ltd.
3655 Bonneville Place
Burnaby, B.C.
Canada V3N 4S9

Distributor: Natural Factors Nutritional Products, Inc.
1111 80th Street SW, Suite 100
Everett, WA 98203

Text of Side Panel: The revolutionary new SlimStyles™ Meal Replacement Program is a safe, highly effective and clinically proven weight loss and weight maintenance system, developed through intensive university-based research to make weight loss simple, comfortable and maintainable for life.

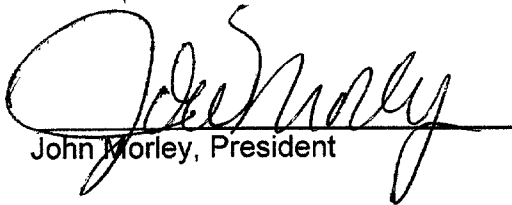
Text on PDP: Clinically Proven Appetite & Weight Control Program

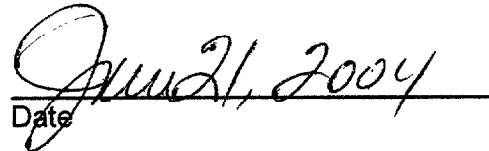
Name of dietary ingredient that is the subject of statement: Whey Protein, PGX™
Proprietary Blend (Highly purified fiber blend processed using advanced proprietary technology: Konjac-mannan (Amorphophallus konjac K. Koch) (root), Sodium Alginate (Laminaria digitata), Xanthan Gum), Lecithin, Medium Chain Triglycerides, Stevia Powdered Extract (leaf)

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Name of the dietary supplement: Natural Factors

I represent the information presented to be accurate and in compliance with supplement label regulations.


John Morley, President


Date